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## FIXATION SYSTEM FOR IMPLANT ELEMENTS

## TECHNICAL FIELD

5 A system for *in vivo* anchoring of implants to a biological tissue or another implant, which system comprises an implant having a pre-treated surface of a given surface roughness and a given chemical composition and on said pre-treated surface one or more layers of material with a phase having the capacity following wetting with a liquid to form a chemically bonded ceramic material.

10 The present invention relates to anchoring systems with binding agent systems of the hydrating cement system type, in particular of aluminates, silicates, phosphates, sulphates and combinations thereof, preferably having calcium as the major cat-ion. The invention is especially intended for dental and orthopaedic implants.

## 15 STATE OF THE ART AND PROBLEM

For implants that are to interact with the human body, it is an advantage with implant materials that due to their biocompatibility provide an optimal fixation or anchoring of the implant to the biological tissue, e.g. bone. Even small gaps may lead to small movements, micromotions, between implant and the tissue, which increase the risk of  
20 implant loosening, e.g. due to formation of zones of fibrous tissue at the implant-tissue interface. Porosity or cavities in the tissue surface (vacuoles) also reduce the implant fixation. To allow for early loading of an implant and to reduce the risk for long term loosening, high quality early fixation is important.

25 Also, in the case of a coated implant, the anchoring of the coating to the implant surface may be the weak point of the implant system.

In SE 463,493, SE 502,987, WO 00/21489, WO 01/76534, WO 01/76535, PCT/SE02/01480 and PCT/SE02/01481, a material is presented that is primarily  
30 intended for dental purposes but that also in many aspects is well adapted for fixation systems of the present invention.

Coating systems for implants are described in: SE 0200637-7, SE 0203223-3 and SE  
35 0203324-1.

## ACCOUNT OF THE INVENTION

The present invention aims at providing a system based on chemically bonded ceramic materials (CBC-materials), for *in vivo* anchoring of an implant to a biological tissue, such as bone. The implant may be ceramic, polymeric or metallic. The system is

5 characterized by:

- a) Anchoring by hydration of a CBC-material to the surface of the pretreated implant and enhanced by chemical and/or mechanical treatment,
- b) inter-anchoring of individual sub-layers of the CBC-material (by liquid transport
- 10 and co-hydration),
- c) anchoring of the CBC-material to a CBC-paste (by surface treatment and co-hydration),
- d) anchoring of the CBC-paste (and the layered CBC-material) to the biological tissue (by dissolution-precipitation and volume increase).

15

Also, the system should fulfill requirements on implantation system and materials, such as desired porosity and desired thickness to optimize the mechanical property profile, i.e. high shear strength of the inner layer towards the substrate and reduced thickness of each individual layer to eliminate larger defects in the layers.

20

Such a system is provided according to the invention as claimed. Especially, the system comprises *in vivo* anchoring of an implant to a biological tissue or another implant. The system comprises an implant having a pre-treated surface of a given surface roughness and a given chemical composition and on said pre-treated surface one or more layers of

25 a material with a phase having the capacity following wetting with a liquid to form a chemically bonded ceramic material. The material of said one or more layers is in the main non-hydrated prior to said *in vivo* anchoring and said one or more layers has/have the capability to chemically and/or mechanically bind to said implant and/or to an optional paste of a powdered material with a calcium based binder phase having the

30 capacity following wetting with a liquid reacting with it to form a chemically bonded ceramic material.

According to the invention, one or more of the layers and preferably at least the outermost layer is in the main non-hydrated. Following application of the coated

35 implant in a living body, this/these layer(s) will hydrate by reaction with body liquid and/or any especially applied hydration liquid, for example provided by a paste of CBC-material applied onto the outermost layer and/or onto the biological tissue.

According to one aspect of the invention, the implant surface is treated to a given surface roughness. The surface treatment can be accomplished by e.g. a mechanical treatment such as sand blasting or grinding. The surface treatment may also be a  
5 chemical process such as etching including salt melts, oxidation including low-temperature oxidation with species such as ozone, Ca-enriched by surface diffusion and hydration. Through heat treatment of the implant in the presence of Ca a chemically active surface layer can be formed, facilitating a better bond. The heat treatment is preferably performed at temperatures above 1000 degrees Celcius, even more preferred  
10 above 1300 degrees.

According to another aspect of the invention, the given surface roughness of the pre-treated surface of the substrate has a Ra-value of less than 10, preferably less than 5 and most preferred less than 1  $\mu\text{m}$ , but due to practical reasons not smaller than  $Ra = 0.5$   
15  $\mu\text{m}$ . Such a surface roughness has been found to be especially well adapted for the anchoring of an innermost CBC-material layer that is applied by a technique in the group that consists of thermal spraying, flame spraying, Electro Deposition Spraying (EDS), plasma spraying, dipping and spin coating.

According to another aspect of the invention, the given surface roughness of the pre-treated surface of the substrate has a Ra-value of less than 1, preferably less than 0.5 and most preferred less than 0.1  $\mu\text{m}$ , but due to practical reasons not smaller than  $Ra = 0.05$   
20  $\mu\text{m}$ . Such a surface roughness has been found to be especially well adapted for the anchoring of an innermost CBC-material layer that is applied by a technique in the group that consists of Chemical Vapor Deposition (CVD), Physical Vapor Deposition (PVD), laser techniques including laser cladding, Electrolytic Deposition (ED), and sol-gel technique. CVD, PVD or a sol-gel technique is especially preferred. The innermost  
25 layer of CBC-material should be relatively thin, i.e. thinner than any one of the other layers, in order to minimize mechanical stresses in that innermost layer. It is preferred that it has a thickness of less than 10  $\mu\text{m}$ , preferably smaller than 2.0  $\mu\text{m}$ .  
30

After a deposition of the one or more layers, some kind of thinning process of the layer may be beneficial, especially concerning but not limited to the innermost layer. The thinning process includes processes such as grinding and sand blasting or dry etching,  
35 but more preferable chemical treatment including dissolution. In connection with the thinning a partial densification of the layer may be performed by techniques such as drying up of particles and precipitation including sol-gel techniques.

A mechanical anchoring of the first layer to the substrate is achieved by the precipitation of sub-micron (nanometer) size crystallites of hydrates against the substrate surface. The crystallite size is preferable below 100 nm, and more preferable  
5 below 50 nm. The large surface area and thereby extremely high surface energy of such crystallites helps in anchoring the layer to the substrate.

The innermost layer of CBC-material can also preferably be chemically bonded to the implant surface by a pre-treatment of said surface yielding a chemical change of the  
10 surface from the original metallic or ceramic character to an oxide, preferably a double oxide of titanate or aluminate type, of the original implant by treatment involving oxidation, calcination, ion bombarding or thermal pretreatment. In connection with the pre-treatment an inner layer of the CBC-material thus may be formed.

15 According to one aspect of the invention, the number of layers of CBC-material are 1-8, preferably 1-5 and even more preferred 2-5. Each layer outside the innermost one independently has a thickness of less than 50  $\mu\text{m}$ , preferably less than 30  $\mu\text{m}$ , but not smaller than 5  $\mu\text{m}$ . Before hydration, the layers should be relatively dense in terms of porosity, preferably having a porosity below 50 % and even more preferred less than 20  
20 %. During the hydration, the porosity of the layers is reduced to less than 10 %, preferably less than 5 %. In the case of non-thermal deposition techniques, such as spin coating, dipping etc, however, a higher porosity than 50 % is normally achieved.

Furthermore, it is preferred that each layer, including the innermost layer, independently  
25 has a binder phase in the group that consists of aluminates, silicates, phosphates, sulphates and combinations thereof, preferably having cations in the group that consists of Ca, Sr and Ba, calcium based binder phases being preferred and calcium aluminates being most preferred, preferably having a composition between the phases  $3\text{CaO} \cdot \text{Al}_2\text{O}_3$  and  $\text{CaO} \cdot 2\text{Al}_2\text{O}_3$ , most preferably about  $12\text{CaO} \cdot 7\text{Al}_2\text{O}_3$ . The material can be in  
30 crystalline or amorphous state. Preferably, the powdered material has a particle size of 0.1 to 20  $\mu\text{m}$  and more preferred 1 to 10  $\mu\text{m}$  and most preferred 1 to 5  $\mu\text{m}$ .

Accordingly, the different layers of the coating may be composed of different, or the same, CBC-material, hydrated to the same or to different degrees, although preferably  
35 no layer is completely hydrated before the implantation takes place. Hydration will take place, following implantation, by reaction with body liquid and/or any especially applied hydration liquid, for example provided by a paste of CBC-material applied onto

the outermost layer and/or onto the biological tissue. Optionally and possibly in combination with the paste, an additional hydration liquid may be provided to the coating layers of the implant, before application of the paste and before implantation takes place, e.g. by dipping, spraying, spin coating or tape casting the coated implant in/with such an additional hydration liquid.

According to another aspect of the invention, the system also comprises a paste of a powdered material with a calcium based binder phase having the capacity following wetting with a liquid reacting with the binder phase to hydrate to a chemically bonded ceramic material of any one of the above mentioned types, which powdered material is slurried in said liquid reacting with the binder phase to form said paste, said paste being adapted to provide an *in vivo* formed interface between said outermost layer and said biological tissue, and preferably having an initial viscosity, directly upon mixing of its powdered material and its liquid reacting with the binder phase, of less than 100,000 cP, preferably less than 10,000 cP.

An organic (polymeric) constituent may be added to the Ca based cement system, especially to the paste. This organic additive is used to achieve suitable rheological properties, low water/cement-ratio and to act as a complementary binding system. This phase also yields the system a more visco-elastic behavior with increased strength. Further aspects are described in co-pending patent application SE-A0-0302844-6, the contents of which are incorporated herein by reference.

Most beneficially, the powdered material of the paste has the form of granules, preferably of a size below 1 mm, more preferred below 0.5 mm and most preferred below 0.4 mm and having a granule compaction density above 35 %, preferably above 50 % most preferred above 60%.

By using granules the w/c ratio (water/cement ratio) can be lower than for the loose powder. The flow-ability of the material is higher when it is granulated. By using highly compacted small granules, the shaping of the paste can take place in a subsequent step, without any remaining workability limitations of highly compacted bodies. A facilitated shaping in such a subsequent step, such as kneading, ultrasound etc., can be made while retaining a mobility in the paste system that has a high final degree of compaction, exceeding 35 %, preferably exceeding 50 %, even more preferred exceeding 60 %.

- According to one aspect of the paste, the granules preferably exhibit a degree of compaction above 60 %, even more preferred above 65 % and most preferred above 70 %. Preferably, the granules have a mean size of at least 30  $\mu\text{m}$ , preferably at least 50  $\mu\text{m}$  and even more preferred at least 70  $\mu\text{m}$ , but 250  $\mu\text{m}$  at the most, preferably 200  $\mu\text{m}$  at the most and even more preferred 150  $\mu\text{m}$  at the most, while the powder particles in the granules have a maximal particle size less than 20  $\mu\text{m}$ , preferably less than 10  $\mu\text{m}$ . It should hereby be noted that it is only a very slight proportion of the powder particles that constitute particles having the maximal particle size. The particle size is measured by laser diffraction. The highly compacted granules are manufactured by the powdered material being compacted to the specified degree of compaction, by cold isostatic pressing, tablet pressing of thin layers, hydro-pulse technique or explosion compacting e.g., where after the material compacted accordingly is granulated, for example crushed or torn to granules of the specified size.
- 15 In the present anchoring system, the paste has the beneficial function of filling the gap between the implant and the biological tissue, and filling any vacuoles or cavities in the surface of the bone tissue. Also, due to its biocompatibility or bioactivity, it provides for an improved anchoring to the bone tissue and to the outermost layer of the coating, which outermost layer is surface treated in order to improve the anchoring to the paste.
- 20 Suitably, the surface of the outermost layer has a Ra-value less than 20  $\mu\text{m}$  and even more preferred Ra less than 10  $\mu\text{m}$ . However, especially in connection with an embodiment with only one single layer, most preferably applied by PVD technique, this layer preferably has a surface roughness with  $Ra < 1 \mu\text{m}$ , even more preferred  $Ra < 0.5 \mu\text{m}$  and most preferred  $Ra < 0.1 \mu\text{m}$ , but not smaller than 0.05  $\mu\text{m}$ . Such a surface roughness of the outermost layer may however also be conceivable in case of more than
- 25 one layer.
- According to yet another aspect, the anchoring system has the capacity to form apatite *in-situ*. By capacity to form apatite in-situ it is hereby meant that the system comprises the components that are necessary for the formation of different types of apatite, hydroxyapatite or fluoride-apatite ( $\text{Ca}_5(\text{PO}_4)_3\text{OH}$  and  $\text{Ca}_5(\text{PO}_4)_3\text{F}$ , respectively) for example, and optionally some other biologically favourable phase, and that the system allows for such phases to be formed during and/or after the hydration reaction. Hereby, the advantage is at least attained that apatite need not be added as a separate additive.
- 30 The material formed can be said to constitute a chemically bonded ceramic composite that exhibits many advantages as a coating layer on an implant material. The formation of apatite in the material is a sign of the material being bioactive and co-operating with
- 35



the body. Furthermore, the distribution of apatite will be homogeneous in the material, also in contact zones against biological material. The formation of apatite in such contact zones is especially favourable for the anchoring. Another advantage for the formation of apatite is that the environment is basic. Since apatite is an endogenous substance, the anchoring system will result in excellent anchoring properties with a very tight union between the implant material and the biological tissue. The integration with the surroundings having a content of apatite is very important.

Surprisingly, it has been found that a calcium based cement system comprising water soluble phosphate or a phase that has the capacity to form water soluble phosphate, at a boundary or a gap between a biological tissue and an implant material, not only provides for the formation of a chemically bonded ceramic composite comprising apatite, but also leads to a faster healing of the bone. It has been found that a chemical and biological integration takes place, that leads to an additional surface growth that chemically diminishes the gap between the biological tissue and the implant material, but that also, due to the presence of apatite, will result in a faster biological sealing of the gap. The healing or growing process of the bone is favoured by an early fixation (less micromotion leading to less fibrous tissue) and by the supply of calcium and phosphate and carbonate from the cement- body liquid system. The dissolution-precipitation of the Ca-based system process is able to close large gaps ( mm size), and by the volume increase related to the formation of hydrates the mass increase in point contacts to biological tissue will provide for further early fixation.

Accordingly, calcium is taken from the calcium based cement system, a calcium aluminate system e.g. Below a surface layer of formed apatite, the content of Ca will therefore be somewhat reduced, which leads to an increased formation of gibbsite phase in the produced ceramic material. The extension of this gibbsite phase may be controlled by the content of Ca and the addition of phosphate in the contact zone.

Another aspect of the formation of hydroxyapatite (formation of HAP) in connection with the general mechanism at hardening comprising dissolving and depositing, is that the system may act to favour healing of damaged bone tissue. Hereby, the biological material that has lost its hard material (its biologically formed apatite) is remineralised by Ca-aluminate reacting with body liquid to form hydrates including apatite. The material is dissolved, i.e. becomes a solution and ions such as calcium, aluminate, phosphate, hydroxyl and optional additives, such as fluoride, is deposited as hydrates in

all voids, including those coming from previous bone decay. Also other bone materials can be favoured in healing in a corresponding manner, e.g. related to osteoporosis etc.

According to another aspect of the invention, said substrate is an implant of a ceramic,  
5 metallic or polymeric material, preferably a material chosen from the group that consists of titanium, stainless steels, alumina, zirconia and medical grade plastics.

Other additives and aspects of the system may follow that which is described in SE  
463,493, SE 502,987, WO 00/21489, WO 01/76534, WO 01/76535, PCT/SE02/01480  
10 and PCT/SE02/01481, the contents of which are incorporated herein by reference.

#### DESCRIPTION OF DRAWINGS

In the following, the mechanism at implanting will be described in greater detail with  
reference to a preferred embodiment.

15

Fig. 1 shows an outer part of an implant with a coating, as seen in cross-section,  
Fig. 2 shows the part according to Fig. 1, provided with an extra, outermost layer, as  
seen in cross-section,

Fig. 3 shows the part according to Fig. 2 immediately after it has been implanted  
20 against a biological wall, as seen in cross-section,

Fig. 4 show the system according to Fig. 3, after about one hour,

Fig. 5 shows the system according to Fig. 3-4 after healing,

Fig. 6 shows an image of hydrates formed after 24 h in rabbit femur.

25 In the figures, detail no. 1 symbolises a metal, ceramic or polymeric implant. Fig. 1  
shows how a coating layer 2 of a CBC-material has been applied and optionally  
hydrated. Fig. 2 shows how an extra, outermost layer 3 has been applied on the coating  
2. The coating layer 2 suitably exhibits a thickness of less than 2  $\mu\text{m}$ . The outer layer 3  
is thicker (although not apparent from the Figures), but suitably not thicker than 20  $\mu\text{m}$ .  
30 The outer layer 3 is composed of non-reacted CA (without any hydration liquid) that  
preferably comprises phosphate. Fig. 2 also shows that a paste 5 of CBC-material has  
been applied onto the outer layer 3, just prior to the implantation operation to take place.

Fig. 3 shows how the implant 1 with the coating layer 2, the outer layer 3 and the paste  
35 5 has been implanted against a biological wall in existing hard tissue, usually bone  
tissue 4, of the patient. Immediately after the implantation, there is a gap x of 10  $\mu\text{m}$   
magnitude in average distance between the outer surface of the outer layer 3 of the

implant and the hard tissue, which gap always will arise even if the implant is put completely in abutment with the hard tissue. Only point contacts exist. In point contacts (not shown in the figure), however, the outermost layer will during hydration - due to volume/mass increase - enlarge the contact surface. Also, there may be vacuoles 6 in the hard tissue, where the hard tissue is damaged and may have lost its possibility to remineralise. In the shown, preferred embodiment of the present invention including the paste 5, the paste 5 however beneficially fills both the gap x and any vacuoles 6.

Fig. 4 shows how the outer, non-reacted layer 3 has hydrated to a hydrated layer 3', in which case 1-3  $\mu$ m surface growth normally has occurred by chemical mass growth on the outer layer 3, 3'. This mass growth depends on an uptake of water, body fluid or hydration liquid, in the non-reacted layer 3. Also the paste 5 has hydrated to form a hydrated layer 5', also including a part 6' that fills the former vacuole 6.

Fig. 5 shows how the implant 1 has been integrated with the hard tissue 4, after healing 4'. The healing and integration will be extra fast, since Ca-ions and optionally phosphate/apatite are supplied to the area via the coating 2, the outer layer 3 and the paste 5. The biologically induced growth of new bone tissue 4' is united with the outer grown layer 3' and the hydrated paste 5'. The biologically related growth is positively affected by the presence of hydroxyapatite. The size of the gap x has, according to the above, been diminished by the chemical growth of layers 3' and 5', which per se will accelerate the biological filling of new bone tissue 4'. In this case, there has been no growth of new bone tissue in the vacuole 6, since the old bone tissue was damaged here and lacked the possibility to remineralise. It should however be understood that vacuoles in other cases still may have the possibility to develop new bone tissue 4'.

#### EXAMPLE 1

Dental screw implants with diameter 3.70 mm and a length of the thread of 5 mm were implanted in the tibia condyl of adult rabbits. Holes were drilled following the dental implantation procedure involving two drilling steps with tools of increased diameter, followed by creation of threaded holes into which the implants were screwed all to the same depth.

Implant screws were used either mildly sand blasted or with a flame sprayed calcium aluminate surface coating of about 30 microns thickness on the threaded section. The blasted screws were used alone or covered with a calcium aluminate - water based paste, which was applied directly before implantation. The calcium aluminate sprayed

implants were dipped in a 6.5 gr/liter LiCl solution prior to implantation, the purpose of which was to accelerate the curing of the calcium aluminate.

- 5 As the implants were removed 24 hrs after implantation, the maximum removal torque was recorded. Using the non-coated and non-augmented screws as references the application of calcium aluminate, either as a sprayed coating or as a paste, increased the 24 hrs attachment to the bone tissue with 30% and 100%, respectively.

#### EXAMPLE 2

- 10 A transmission electron microscopy (TEM) study of the hydrate grain size was performed on hydrated  $\text{CaOAl}_2\text{O}_3$  plasma-sprayed coatings.

- 15 Implants were put in the femur of rabbits for 24 h. The rabbits were then terminated and the implant fixated and embedded. To obtain TEM samples of the hydrated coatings focused ion beam microscopy (FIB) was used. Cross-sections of the metal-coating interface were produced via cutting with a diamond saw and polished with down to 0.25 micron diamond paste on cloths. Five by five micron TEM-samples were produced from the cross-sections using the FIB. The samples were then imaged in annular dark field STEM mode in a 200 keV FEG TEM (Jeol).

- 20 The hydrates were plate or needle shaped and had a grain size of below 100 nm, see Fig. 6.

#### EXAMPLE 3

- 25 A chemically active surface was produced on a inert alumina implant via pressing a layer of  $\text{CaOAl}_2\text{O}_3$  onto the alumina surface followed by a heat treatment at 1100 degrees Celcius for 6 h. Investigation of the surface composition after heat treatment with X-ray diffraction showed that only crystalline  $\text{CaOAl}_2\text{O}_3$  was present on the surface. The adhesion between the  $\text{CaOAl}_2\text{O}_3$  layer and the implant was very strong as  
30 tested with scratch testing, no coating delamination occurred.

The invention is not limited to the embodiments described above, but can be varied within the scope of the claims.

## CLAIMS

1. A system for *in vivo* anchoring an implant to a biological tissue or another implant, which system comprises an implant having a pre-treated surface of a given surface roughness and a given chemical composition and on said pre-treated surface one or more layers of a material with a phase having the capacity following wetting with a liquid to form a chemically bonded ceramic material, characterised in that the material of said one or more layers is in the main non-hydrated prior to said *in vivo* anchoring and that said one or more layers has/have the capability to chemically and/or mechanically bind to said implant and/or to an optional paste of a powdered material with a calcium based binder phase having the capacity following wetting with a liquid reacting with it to form a chemically bonded ceramic material.
2. A system according to claim 1, characterised in that an outermost layer has a surface treated to a given surface roughness, preferably with  $Ra < 20 \mu m$  and even more preferred  $Ra < 10 \mu m$ , but not smaller than  $0.5 \mu m$ .
3. A system according to claim 1, characterised in that an outermost layer has a surface treated to a given surface roughness, preferably with  $Ra < 1 \mu m$ , even more preferred  $Ra < 0.5 \mu m$  and most preferred  $Ra < 0.1 \mu m$ , but not smaller than  $0.05 \mu m$ .
4. A system according to any one of the preceding claims, characterised in that said one or more layer has/have a porosity below 50 %, more preferable below 20% and most preferred below 10%.
5. A system according to any one of the preceding claims, characterised in that said chemical binding to the implant is caused by a pre-treatment of the implant surface, giving a chemical change of the surface to form an oxide, preferably a double oxide of titanate or aluminate type.
6. A system according to claim 5, characterised in that said pre-treatment comprises a treatment in the group that consists of oxidation including low-temperature oxidation, and thermal treatment including solid state diffusion and ion bombarding.

7. A system according to any one of the preceding claims, characterised in that said mechanical binding to the implant is caused by precipitation of sub-micron size crystallites of hydrates against the implant surface.
- 5 8. A system according to claim 7, characterised in that the crystallite size is less than 100 nm and more preferably less than 50 nm.
9. A system according to any one of the preceding claims, characterised in that in said paste its powdered material is slurried in said liquid reacting with the binder phase, said paste being adapted to provide an *in vivo* formed interface between said outermost layer and said biological tissue or implant, and said paste preferably having an initial viscosity, directly upon mixing of its powdered material and its liquid reacting with the binder phase, of less than 100,000 cP, preferably less than 10,000 cP.
- 10 15 10. A system according to claim 9, characterised in that the powdered material of the paste has the form of granules, preferably of a size below 1 mm, more preferred below 0.5 mm and most preferred below 0.4 mm and having a granule compaction density above 35 %, preferably above 50 % most preferred above 60%.
- 20 11. A system according to any one of the preceding claims, characterised in that the given surface roughness of the pre-treated surface of the implant has a Ra-value of less than 10, preferably less than 5 and most preferred less than 1  $\mu\text{m}$ , but not smaller than 0.5  $\mu\text{m}$ .
- 25 12. A system according to any one of the preceding claims, characterised in that the given surface roughness of the pre-treated surface of the implant has a Ra-value of less than 1, preferably less than 0.5 and most preferred less than 0.1  $\mu\text{m}$ , but not smaller than 0.05  $\mu\text{m}$ .
- 30 13. A system according to any one of the preceding claims, characterised in that an innermost layer has a thickness in the interval from angstrom level to less than 10  $\mu\text{m}$ , preferably less than 2.0  $\mu\text{m}$ , and that it preferably is applied onto the implant surface by a technique in the group that consists of Chemical Vapor Deposition (CVD), Physical Vapor Deposition (PVD), Thermal Spray Deposition (TSD), Electrolytic Deposition (ED) and sol-gel technique.
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14. A system according to any one of the preceding claims, characterised in that the number of layers are 1-8, preferably 1-5 and even more preferred 2-5.
- 5 15. A system according to any one of the preceding claims, characterised in that it comprises at least two layers and that each layer outside the innermost one independently has a thickness of less than 50  $\mu\text{m}$ , preferably less than 30  $\mu\text{m}$ , but not smaller than 5  $\mu\text{m}$ .
- 10 16. A system according to any one of the preceding claims, characterised in that said one or more layers is/are thinned, preferably by a process in the group that consists of grinding, sand blasting, dry etching and chemical treatment including dissolution.
- 15 17. A system according to claim 16, characterised in that in connection with said thinning a partial densification of said one or more layers is performed, preferably by drying up of particles and precipitation including sol-gel techniques.
- 20 18. A system according to any one of the preceding claims, characterised in that each layer independently has a binder phase in the group that consists of aluminates, silicates, phosphates, sulphates and combinations thereof, preferably having cations in the group that consists of Ca, Sr and Ba, calcium based binder phases being preferred and calcium aluminates being most preferred, preferably
- 25 having a composition between the phases  $3\text{CaO} \cdot \text{Al}_2\text{O}_3$  and  $\text{CaO} \cdot 2\text{Al}_2\text{O}_3$ , most preferably about  $12\text{CaO} \cdot 7\text{Al}_2\text{O}_3$ .
- 30 19. A system according to any one of the preceding claims, characterised in that said implant is an implant of a ceramic, metallic or polymeric material, preferably a material chosen from the group that consists of titanium, stainless steels, alumina, zirconia and medical grade plastics.

## ABSTRACT

A system for *in vivo* anchoring an implant to a biological tissue or another implant, which system comprises an implant having a pre-treated surface of a given surface roughness and a given chemical composition and on said pre-treated surface one or  
5 more layers of a material with a phase having the capacity following wetting with a liquid to form a chemically bonded ceramic material. The material of said one or more layers is in the main non-hydrated prior to said *in vivo* anchoring and said one or more layers has/have the capability to chemically and/or mechanically bind to said implant and/or to an optional paste of a powdered material with a calcium based binder phase  
10 having the capacity following wetting with a liquid reacting with it to form a chemically bonded ceramic material.

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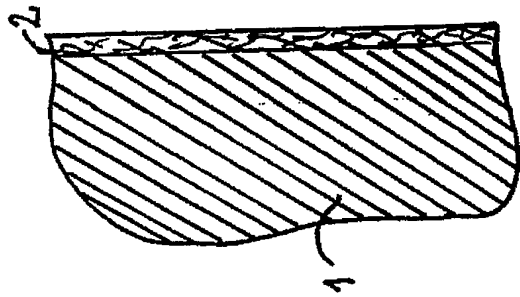


Fig. 1

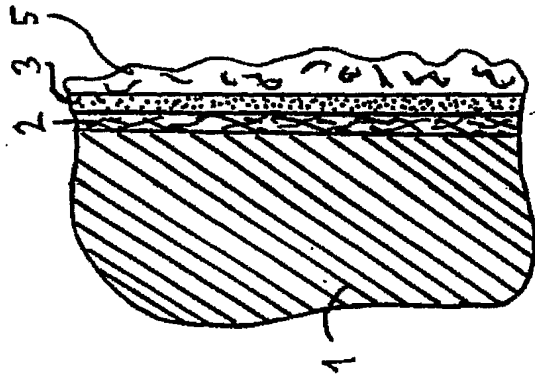


Fig. 2

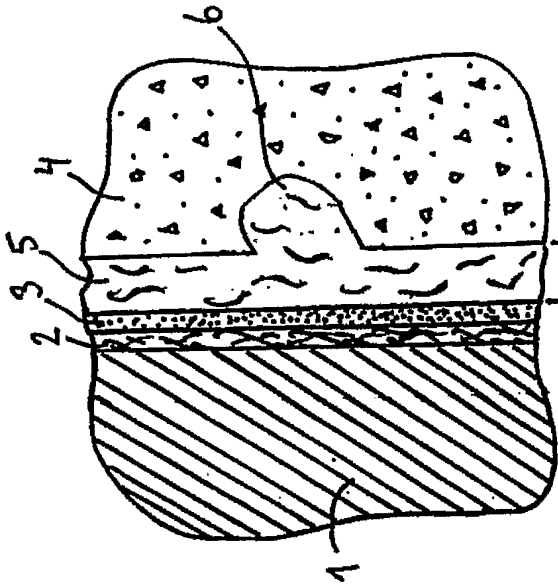


Fig. 3

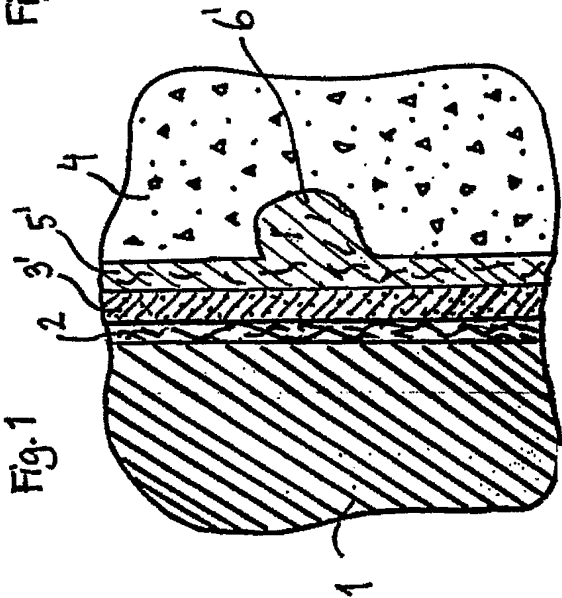


Fig. 4

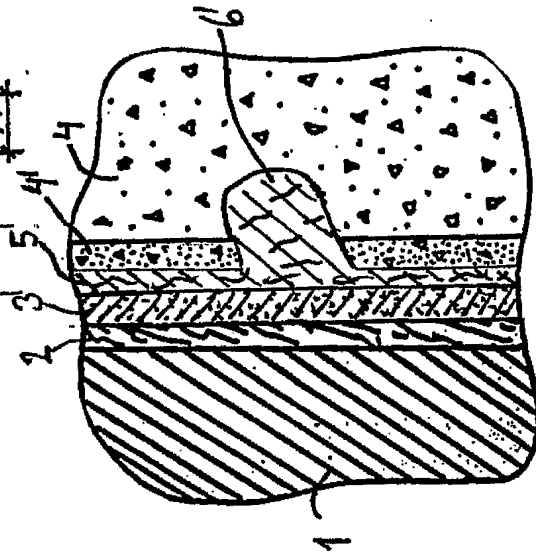


Fig. 5

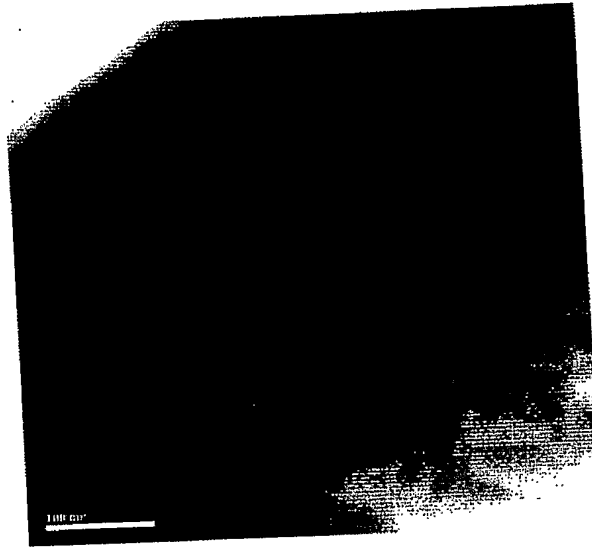


Fig. 6

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